Effect of wearing an N95 respirator on infrared tympanic membrane temperature measurements

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Abstract

To determine the impact of wearing an N95 filtering facepiece respirator (N95 FFR) on tympanic temperature measurements. TMT measurements, with and without wearing an N95 filtering facepiece respirator (N95 FFR) were obtained at the onset and termination of 1 h of treadmill exercise in 21 subjects, and at staggered time intervals (0, 20, 40, 60 min) during combined sedentary activity and exercise of another 46 subjects, to determine any effect on TMT. A total of 877 TMT measurements were obtained that demonstrated a mean TMT increase of 0.05 °C in the first study group ($p = 0.04$) and a 0.19 °C decrease in the second study group ($p < 0.001$) with the wearing of an N95 FFR, both of which were lower than controls. Wearing an N95 FFR for 1 h, at different levels of activity, results in significantly lower TMT values than not wearing an N95 FFR, but the magnitude of the changes would likely have minimal clinical significance.

Keywords

N95 filtering facepiece respirators; Tympanic membrane temperature

1 Introduction

Protective facemasks, such as filtering facepiece respirators (FFR) and medical/surgical masks, are frequently used by patients for personal protection from airborne infectious agents carried on small particles or droplet nuclei (FFR), as well as for protection from large droplets and to limit dissemination of patient-expelled respiratory tract pathogenic secretions (medical/surgical masks and FFR). Temperature readings are routinely obtained on patients to screen for fever and, since 1986, the use of infrared thermometers for tympanic membrane temperature (TMT) measurements has become widespread in hospitals, clinics and medical practitioners' offices because of their ease of use, rapid results, data storage

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Conflict of interest The authors declare that they have no conflict of interest.

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The authors declare that the experiments comply with the current laws of the United States of America.

capability, cleanliness, safety and assumed relationship to core body temperature [1, 2]. Prior research has shown that local alterations of facial, scalp and neck temperatures can impact TMT, presumably due to thermal effects on local dermal blood vessels that share circulation with vessels supplying the tympanic membrane [3–5]. Increased skin temperature, with concomitant warming of local dermal vessels in that area of the face covered by protective facemasks, results from a barrier effect upon local heat release mechanisms (i.e., facial skin heat convection, radiation and sweat evaporation) and from the trapping of warmed exhaled air in the mask deadspace [6–8]. Therefore, it is plausible that the TMT of patients wearing protective facemasks may be elevated over baseline values and thus negatively impact the clinical utility of the measurements. The N95 class of FFR (N95 FFR) is the most commonly used respirator in U.S. healthcare [9], but limited scientific data is available about its impact on TMT [10]. This investigation is part of the National Institute for Occupational Safety and Health's (NIOSH) Project BREATHE (Better Respiratory Equipment using Advanced Technologies for Healthcare Employees), which is addressing respiratory protection needs of healthcare workers [11] and some of the results of which have previously been published [12, 13]. The current study was undertaken to assess the impact of wearing N95 FFRs on infrared TMT measurements. This data could be useful to healthcare personnel, respiratory protection program managers, personal protective equipment researchers, and governmental agencies (e.g., border security, airport security, etc.) that utilize mass temperature screening during infectious disease outbreaks, when protective face-mask use may be widespread, to determine the need for further evaluation or quarantining [10].

2 Materials and methods

Data for the current study were drawn from subjects in two separate Project BREATHE [11] reports (investigations a (not published) and b [12]) totaling 67 individuals. Investigation a subject demographic mean values (SD) for men (n = 12) were age 22.6 years (2.7), height 180.8 cm (7.9), weight 84.1 kg (16.5) and Body Mass Index (BMI) 25.7 kg/m^2 (4.8), and for women (n = 9) were age 23.7 years (3.3), height 166.4 cm (4.0), weight 65.6 kg (6.5) and BMI 23.7 kg/m^2 (2.6). Investigation b [12] mean values (SD) of non-pregnant women subjects (n = 22) were age 26.1 years (4.0), height 167.4 cm (5.9), weight 67.5 kg (9.5) BMI 24.0 kg/m^2 (3.2), and for pregnant women subjects (n = 22; 13–35 weeks gestation) were age 27.9 years (3.1), height 166.6 cm (5.4), weight 75.2 kg (18.9), BMI 26.8 kg/m^2 (6.3) and mean gestation period 20.6 weeks (4.6). All subjects underwent a screening medical examination by a licensed physician immediately prior to being studied and none had evidence of ear infection or was febrile. Studies a and b [12] were approved by the NIOSH Human Subjects Review Board, and all subjects provided oral and written informed consent.

Subjects first underwent Occupational Safety and Health Administration (OSHA) respirator quantitative fit testing [14] to ensure adequate fit and all subjects passed fit testing on the N95 FFR models used in investigations a and b [12] (none equipped with an exhalation valve). TMT was measured with a Welch/Allyn Pro 4000 infrared thermometer (Braun GmbH, Kronberg, FRG), a factory-calibrated unit with a manufacturer-rated accuracy of 0.2 °C that has been previously validated [15]. The TMT measurements followed standard technique [16] that consisted of (1) a new probe cover being placed for each measurement,

(2) gentle traction being applied superiorly and posteriorly to the pinna to straighten the ear canal as the measuring probe was gently inserted into the external auditory meatus far enough to provide a good seal between the probe and ear canal wall, and (3) direction of the tip of the probe towards the ipsilateral eye and rotation of the body of the infrared thermometer in line with the mandible ramus ("telephone handle" position), followed by pushing and releasing the activation button and listening for the audible beep that signaled a TMT recording. Investigation a subjects (n = 21) had their TMT measured from the right ear at the onset (0 min) and termination (60 min) of treadmill walking (5.6 km/h, 0° incline) while wearing four different models of randomized N95 FFRs [two rigid cup-shaped (3M 1860 model and a 3M Prototype), one flat fold (3M 1870 model), one pleated (3M Prototype); 3M Company, St Paul, MN, US] for 1 h each (trials) and 1 h with no N95 FFR (controls) on a single day of testing, with a minimum of a 30 min respite (no respirator) between consecutive tests. Investigation b [12] subjects (n = 46) had TMT measured from the left ear at 0, 20, 40, and 60 min during contiguous 20 min sessions each of (1) standing, (2) pedaling a reclining bicycle ergometer (60 pedal cycles per min, 50 W resistance), and (3) upright sitting while wearing either a randomized pre-moulded, cup-shaped N95 FFR [Moldex Model 2200, Culver City, CA, US (n = 12)] or a flat-fold N95 FFR [3M 9210 (n = 34)] and during the same activities without a respirator (controls) on a single day of testing. The work rates used for investigations a and b [12] are considered low-to moderate [8], as would routinely be experienced by healthcare workers. All 877 TMT measurements in the study were taken by the same physician researcher to reduce inter-observer variability. Data were collected in a physiology laboratory with mean temperature 20.5 °C (1.0), relative humidity 38.8 % (13.4) and barometric pressure 739.1 mmHg (5.1).

Statistical analysis data from investigations a and b [12] were first calculated for group mean (control vs. respirator trial), SD, and 95 % confidence interval (C.I.) of the mean followed by the calculation of total change [Delta (Δ)] in TMT from the onset to the end of each study protocol. Independent samples *t* tests were carried out to determine a mean difference in Δ TMT between control and respirator trials. Statistical significance was accepted when $p <$ 0.05 with equal variances not assumed, and all analyses were performed using a statistical software package (SPSS v.18, IBM, Somers, NY).

3 Results

For investigations a and b [12], TMTs and the Δ values were analyzed from 197 separate 1 h exercise periods that included 130 h of wearing an N95 FFR and 67 h not wearing a respirator (Tables 1, 2). Investigation a results indicated that wearing an N95 FFR during treadmill exercise (5.6 km/h) for 1 h resulted in a mean TMT Δ value of 0.05 °C (0.28) that was significantly lower ($p = 0.04$) than the 0.21 °C (0.31) TMT Δ noted for controls (Table 1). Investigation b [12] revealed a mean TMT Δ value of −0.19 °C (0.32) with wearing an N95 FFR that was significantly different ($p = 0.001$) from the TMT Δ of 0.05 °C (0.32) noted for controls over 1 h of combined sedentary activity and exercise (Table 2).

4 Discussion

Our data indicate that wearing an N95 FFR over 1 h, at combined sedentary postural activities and bicycle ergometer exercise [12], and during treadmill exercise at a low-moderate work rate (investigation a), results in mean TMT Δ values that are lower than when no N95 FFR is worn (Tables 1, 2). Normal TMT readings in adults range from 35.5 °C to 37.5 °C [17] with fever considered ≥38.0 °C and hypothermia at<35 °C so that, although these mean TMT Δ values in the current study were statistically significant, their absolute values would likely be of doubtful clinical importance. These findings are perhaps not surprising given that recent research has noted only mild core temperature increases of ≤0.13 °C for N95 FFR and surgical masks [7, 8] over 1 h of exercise that are not substantially different from the 0.10 °C core temperature increase with 1 h of exercise at a low work rate without a protective facemask. Yip et al. [10] reported that wearing an N95 FFR during healthcare worker activities over 30 min resulted in a mean TMT Δ of 0.03 °C (0.45) in 31 subjects (study population was 2/3 women) that is similar to our findings for subjects from investigation a. The current study's reported lower Δ values, when comparing respirator trials with controls, may be attributable to different mechanisms. The respiratory tract is responsible for 10–15 % of body heat elimination (depending on level of activity and environmental conditions) [6] and the use of N95 FFRs results in an increase in the respiratory rate and minute volume [18, 19], such that greater respiratory heat dissipation may account for our observed lower mean TMT Δ values with N95 FFR use. Similarly, the increased minute ventilation associated with pregnancy [20] would serve to augment respiratory heat dissipation and may have impacted the results in investigation b [12] where a downward trend in TMT from baseline is observed throughout the 1 h of N95 FFR wear compared with controls (Table 2). It may be that some patients with conditions associated with augmented respiratory rates (e.g., pulmonary infections, anxiety [21], etc.), who manifest a further increase in their already elevated minute ventilation when wearing protective facemasks, may have even lower Δ TMT values than noted in the current study. The shorter exercise period (20 min) of investigation b [12] compared with investigation a (60 min) also accounts partially for the former's lower TMT Δ values when wearing an N95 FFR. Additionally, the current study's subjects had a longer period of N95 FFR wear than Yip et al. [10] that could have allowed for more heat dissipation. Also, as noted in investigation b [12], during the first few minutes after the onset of exercise, core temperature drops due to the body's redistributing blood from the core to working muscles [22]. Ambient temperatures can also affect TMTs, but increases in core temperature have been shown to be largely independent of ambient temperatures between 5 and 30 °C [23], a range that encompasses those of investigations a and b [12].

Limitations of the current study include the fact that TMTs were measured for 1 h periods only, so that the impact on TMT of protracted N95 FFR use for multiple hours or days is unknown. However, prior research [7] has demonstrated no significant effect in core temperatures during up to 2 h of wearing N95 FFRs at low-moderate work rates, and investigation a included single day testing in which subjects wore N95 FFRs for a total of 4 h with only 30 min breaks between successive hours of exercise and no clinically significant changes in TMT were noted. Though recent data has indicated that elevated BMI and age may have a relationship with thermal discomfort experienced with wearing N95 FFRs [24], we did not analyze the possible impact of BMI or age on TMT because few of our subjects were overweight (9 %) or age ≥30 years (12 %). Only adult subjects were enrolled, so that we cannot comment on the impact of protective facemask wear on children. Only three styles of N95 FFR (i.e., cup-shaped, flat-fold, pleated) were tested, so that we cannot comment on the impact on TMT measurements of other styles (e.g., duck bill, tri-fold, etc.) or N95 FFRs that have an exhalation valve. Only one model of infrared thermometer was used for the study, so that we are unable to extrapolate our findings to other models. We did not test medical/surgical masks, but recent findings demonstrating a minimal core temperature increase (0.13 °C) with the wearing of surgical masks, over 1 h at a low-moderate work rate (5.6 km/h) [8], suggest that mean Δ TMT values of patients wearing a surgical mask will not be significantly different from those noted with N95 FFRs in the current study. Given that most inpatients are relatively sedentary (bedridden) and that 2/3 of the time in investigation b [12] was spent in sedentary activity (sitting, standing), it may be that its data are more reflective of the effect of N95 FFR wear on most hospitalized patients, but this is speculative.

5 Conclusions

Our data indicate that wearing an N95 FFR over 1 h, at either combined sedentary/exercise activities or during treadmill exercise at a low-moderate work rate, results in mean TMT Δ values that are below those noted without an N95 FFR (Tables 1, 2). Although these mean TMT Δ values are statistically significant ($p < 0.05$), their absolute values are slight and would have doubtful clinical impact.

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Table 1

Infrared tympanic membrane temperatures of 21 subjects wearing four models of N95 filtering facepiece respirators for 1 h each (trials) and no respirator for 1 h (controls) while treadmill exercising (5.6 km/h)

Time	Control (n = 21)		Respirator (n = 84)	
	Mean ± SD	95 % CI	Mean ± SD	95 % CI
0 min	36.46 ± 0.33	36.30–36.61	36.65 ± 0.33	36.57–36.72
60 min	36.67 ± 0.40	36.49–36.86	36.70 ± 0.35	36.63–36.78
Delta (0–60 min)	0.21 ± 0.31*	0.07–0.35	0.05 ± 0.28*	0.00–0.11

*Delta statistical result (t = 2.077, $p = 0.047$, CI = 0.002–0.309)

Table 2

Infrared tympanic membrane temperatures of 46 subjects over 1 h of combined sedentary (standing and sitting) and treadmill (5.6 km/ h) activities while wearing an N95 filtering facepiece respirator (trials) and no respirator (controls)

Time	Control (n = 46)		Respirator (n = 46)	
	Mean ± SD	95 % CI	Mean ± SD	95 % CI
0 min	36.71 ± 0.37	36.60 to 36.82	36.73 ± 0.35	36.63 to 36.84
20 min	36.68 ± 0.38	36.57 to 36.79	36.55 ± 0.36	36.44 to 36.66
40 min	36.78 ± 0.40	36.66 to 36.90	36.62 ± 0.36	36.51 to 36.73
60 min	36.76 ± 0.37	36.65 to 36.87	36.54 ± 0.37	36.43 to 36.65
Delta (0–60 min)	0.05 ± 0.32*	−0.04 to 0.14	−0.19 ± 0.32*	−0.28 to −0.09

*Delta statistical result (t = 3.517, *p* = 0.001, CI = 0.104–0.374)